REMARKS

Claims 1-16 are pending in the application and have been examined. The allowance of Claims 1-7 is noted with appreciation. Claims 8-16 stand rejected. Applicants respectfully request reconsideration and allowance of Claims 8-16.

The Rejection of Claims 8-16 Under 35 U.S.C. § 112, First Paragraph

The Examiner has rejected Claims 8-16 under 35 U.S.C. § 112, first paragraph, as not being enabled by the specification. According to the Examiner, the specification does not reasonably provide enablement for all types of cancer or proliferative diseases. Moreover, the Examiner states that proliferative diseases such as atherosclerosis, psoriasis, and inflammatory diseases such as sepsis and rheumatoid arthritis are not known to be treatable with platinum complexes. Applicants respectfully disagree with the Examiner's position.

First, applicants respectfully submit that atherosclerosis, psoriasis, and inflammatory diseases such as sepsis and rheumatoid arthritis are not within the scope of the term "proliferative disease" as claimed and described in the specification. The Federal Circuit has stated that "[a]lthough the PTO must give claims their broadest reasonable interpretation, this interpretation must be consistent with the one that those of skill in the art would reach." *In re Cortwright*, 49 U.S.P.Q. 2d 1464, 1467 (Fed. Cir. 1999). A similar fact situation was addressed in *In re Seichert*, 196 U.S.P.Q. 208 (C.C.P.A. 1977). In this case, the Board of Appeals ("Board") had sustained the Examiner's rejection of a claim directed to a composition for treating lymphatic congestions under 35 U.S.C. § 112, first paragraph, for lack of enablement. The Examiner had interpreted the term "lymphatic congestions" as including cancer, although the treatment of cancer was not disclosed in the specification. *In re Seichert*, 196 U.S.P.Q. at 211. Applicants argued that this phrase, as used in the specification, is limited to simple lymphatic congestions, i.e., clogged lymph vessels, and does not encompass the causes or results of lymphatic

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congestion. *In re Seichert*, 196 U.S.P.Q. at 212-212. The U.S. Court of Customs and Patent Appeals ("CCPA") agreed with the applicants, noting that the specification contains 15 examples of the treatment of congestions or stoppages of the lymph system and does not mention the use of the composition in the treatment of cancer. *Id.* at 212.

Applicants respectfully point out that one of skill in the art would interpret the term "proliferative disease," as used in the specification, to refer to diseases caused by aberrant proliferation of cells, particularly cancer. The specification emphasizes throughout that the platinum compounds of the invention are used in the treatment of cancer. For example, the specification explicitly characterizes the invention as relating to "treating cancer using the platinum compounds" (Specification, page 1, lines 7-8; page 3, lines 1-2). Moreover, the specification states that some of the inventive compounds include tocopherol to reduce or prevent side effects associated with the anticancer effects of chemotherapy and that other inventive compounds include a targeting group, such as folic acid, which binds to overexpressed folate receptors on cancer cells (Specification, page 4, lines 8-10 and lines 23-29). The use of the compounds of the invention for the treatment of specific cancers is also disclosed (see, e.g., Specification, page 9, lines 8-14; page 22, line 5 to page 23, line 13; Table 1). Importantly, the specification does not mention the use of the platinum compounds for the treatment of atherosclerosis, psoriasis, and inflammatory diseases such as sepsis and rheumatoid arthritis. Accordingly, applicants respectfully submit that the Examiner's interpretation of "proliferative diseases" is contrary to the meaning of this term disclosed in the specification and inconsistent with the interpretation of this term by one of skill in the art.

Second, applicants respectfully disagree that the treatment of cancer with the compounds of the invention is not fully enabled by the specification. The Examiner has cited *In re Buting*, 163 U.S.P.Q. 689 (C.C.P.A. 1969) to support his position that Claims 8-16 are not enabled. The

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claim at issue in *In re Buting* was directed to a method of treating a malignant condition selected from the group of leukemias, sarcomas, adenocarcinomas, lymphosarcomas, melanomas, myelomas, and ascetic tumors by administering a bis[b-(2-methlyaziridino)ethyl] sulfone compound. The applicant had presented evidence in the specification and by affidavit of the efficacy of two of these compounds against a spectrum of leukemias, and ascetic and solid tumors in experimental mice, and efficacy of one of these compounds against Hodgkin's disease and chronic myelogenous leukemia in two human patients. *In re Buting*, 163 U.S.P.Q. at 689. The applicant had acknowledged that the application was specifically directed toward the treatment of human subjects. Accordingly, the CCPA noted tests demonstrating effectiveness of compounds "must be viewed with respect to the utility asserted," and did not consider the animal model data. *In re Buting*, 163 U.S.P.Q. at 691. Accordingly, the court held that the evidence of efficacy in human subjects, which was limited to one compound and two types of cancer, was not commensurate with the broad scope of utility asserted. *Id.*

Applicants point out that *In re Buting* has been distinguished by the Board. See, e.g., *Ex parte Chwang*, 231 U.S.P.Q. 751, 752 (Bd. Pat. App. Int. 1986) (noting that "substantial progress has been made in the study and treatment of cancer in the intervening years."); *Ex parte Krepelka*, 231 U.S.P.Q. 746, 747 (Bd. Pat. App. Int. 1986) (stating that "[t]he state of cancer treatment has advanced markedly.").

Moreover, applicants respectfully submit that the Federal Circuit has rejected the view expressed in *In re Buting* that anti-cancer efficacy in animal models and cell lines is insufficient to establish enablement and utility of compounds for the treatment of human cancer. *In re Brana*, 34 U.S.P.Q.2d 1436 (Fed. Cir. 1995). The *In re Brana* applicants had provided data showing the action of their compounds against two tumor cell lines, which the Board of Patent Appeals and Interferences ("Board") had argued were inadequate to convince one skilled in the

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art of the utility of the claimed compounds as anti-tumor agents. The Federal Circuit reversed, noting that "the prior art . . . discloses structurally similar compounds to those claimed by the applicants which have been proven *in vivo to* be effective as chemotherapeutic agents against various tumor models." *In re Brana*, 34 U.S.P.Q. 1441. Moreover, the Federal Circuit noted:

> Usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans. Were we to require Phase II testing in order to prove utility, the associated costs would prevent many companies from obtaining patent protection on promising new inventions, thereby eliminating an incentive to pursue, through research and development, potential cures in many crucial areas such as the treatment of cancer. In view of all the foregoing, we conclude that applicants' disclosure complies with the requirements of 35 U.S.C. § 112 Para. 1.

In re Brana, 34 U.S.P.Q. at 1442-1443. Accordingly, applicants respectfully submit that the *In re Brana* court would consider the animal efficacy data presented in *In re Buting* and would find them, together with the human efficacy data, to provide utility and enablement commensurate with the scope of the claim at issue.

Applicants submit the specification expressly describes in detail the anti-cancer activity of a representative platinum compound of the invention. Specifically, Example 5 of the specification describes the cytotoxicity of a representative platinum compound against a panel of seven different cancer cell lines: CI-H460 (ATCC #HTB-177; non-small cell lung cancer), HCT-15 (ATCC #CCL-225; colorectal cancer), OVCAR-3 (ATCC #HTB-161; ovarian cancer), CACO-2 (ATCC #HTB-37; colorectal cancer), MCF-7 (ATCC #HTB-22; breast cancer), HT-29 (ATCC #HTB-38; colorectal cancer), and HCT-116 (ATCC #CCL-247; colorectal cancer) (Specification, page 22, line 5 to page 23, line 13; Table 1). Therefore, the specification provides data on the efficacy of the claimed compounds for the treatment of a wider range of cancers than was disclosed in the specification at issue in *In re Brana*. Moreover, the specification establishes that the platinum compounds of the invention have comparable anti-

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cancer activity to prior art platinum compounds (Specification, page 22, line 5 to page 23, line 13; Table 1). These prior art platinum compounds are well-known to be effective for the treatment of a broad spectrum of cancers, including solid tumors and hematological malignancies (see, e.g., Specification, page 1, lines 10-12).

Accordingly, for all the reasons described above, applicants submit that the invention of Claims 8-16 is fully enabled by the specification. Withdrawal of this ground of rejection is respectfully requested.

Conclusion

In view of the above amendments and foregoing remarks, applicants believe that Claims 1-16 are in condition for allowance. If any issues remain that may be expeditiously addressed in a telephone interview, the Examiner is encouraged to telephone applicants' attorney at 206.695.1783.

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